



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

MAY 27 1999 9 422 '99 JUN -2 P1:22

Mr. Randal R. Buresh  
President  
Oregon's Wild Harvest  
43464 S.E. Phelps Road  
Sandy, Oregon 97055

Dear Mr. Buresh:

This is in response to your letter of May 18, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Oregon's Wild Harvest is making the following statement for its product Ginger:

"Eases Symptoms of Travel Motion"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent, treat, or mitigate disease, namely, motion sickness. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Office, Office of Compliance, HFR-PA340

975-0163

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

HFV-228 (SBenz)

HFV-232 (ABrown)

f/t:HFS-456:rjm:5/26/99:docname:65255.adv:disc37

## *Oregon's Wild Harvest*

May 18, 1999



Office of special Nutritionals (HFS-450)  
Center for Food safety and Applied Nutrition  
Food and Drug Administration  
200 C street  
Washington, D.C. 20204

### Notification of Statements of Nutritional Support

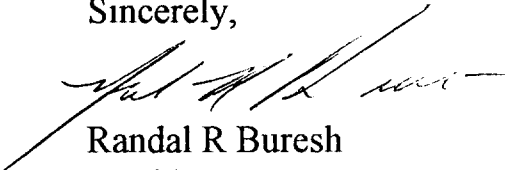
This notification is filed pursuant to section 403 (r) (6) of the federal Food, drug, and Cosmetic Act (FTC Act), 21 U.S.C. ss 343 (r) (6). Please see attachment for a listing of dietary supplements and corresponding statement of nutritional support.

These statements are being accompanied by the required disclaimer pursuant to Section 403 (r) (6) (C) of the Act.

Statements of nutritional support are based on data which render these statements substantiated, truthful and non-misleading

Two copies of this letter and its attachment are enclosed.

Sincerely,



Randal R Buress  
President

65255

| Dietary Supplement   | Brand Name                   | Statement of Nutritional Support                          |
|----------------------|------------------------------|-----------------------------------------------------------|
| Kava Root            | Great Northwest Herb Company | Nutritionally Supports Feelings of Relaxation             |
| Echinacea purpurea   | Oregon's Wild Harvest        | Seasonal support for the body's natural defense system    |
| Echinacea purpurea   | Great Northwest Herb Company | Nutritional Support for the Body's Natural Defense system |
| Cardio-Flo           | Oregon's Wild Harvest        | Nutritional Heart Support                                 |
| Energy Blend         | Oregon's Wild Harvest        | Nutritional Stamina Support                               |
| Muscle Relax         | Oregon's Wild Harvest        | Relaxes Muscle Tension                                    |
| Woman's Monthly      | Oregon's Wild Harvest        | Supports Female Balance                                   |
| Horse Chestnut       | Oregon's Wild Harvest        | Vascular Support for Legs                                 |
| Digestum             | Oregon's Wild Harvest        | Digestive System Support                                  |
| St. John's Wort-Kava | Oregon's Wild Harvest        | Relaxation support                                        |
| Bromovlex            | Oregon's Wild Harvest        | Joint & Connective Tissue Support                         |
| Ginger               | Oregon's Wild Harvest        | Eases Symptoms of Travel Motion                           |